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JPW

Docket No. 72242-AB/JPW/GJG

THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Allan Green et al.  
Serial No.: 09/981,124 Examiner: E. McElwain  
Filed : October 17, 2001 Group Art Unit: 1638  
For : FATTY ACID EPOXYGENASE GENES FROM PLANTS AND USES  
THEREFOR IN MODIFYING FATTY ACID METABOLISM

1185 Avenue of the Americas  
New York, New York 10036  
January 31, 2005

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

SIR:

**RESPONSE TO DECEMBER 29, 2004 COMMUNICATION**

This is a Response to the December 29, 2004 Communication issued by the U.S. Patent and Trademark Office in connection with the above-identified application. A response to the December 29, 2004 Communication is due within one (1) month from the mailing date, i.e. by January 29, 2005. However, because January 29, 2005 falls on a Saturday, the next succeeding day which is not a Saturday, Sunday or Federal holiday, i.e. Monday, January 31, 2005, is considered timely under 37 C.F.R. § 1.7 and this Response is being timely filed.

The December 29, 2004 Communication alleged that applicants' October 15, 2004 Response is not fully responsive to the September 16, 2004 Communication and the February 17, 2004 restriction requirement because applicants have cancelled all original claims and submitted new claims for examination, but allegedly have not elected one of the groups set forth in the February 17, 2004 restriction requirement. The Examiner then alleged that the new claims submitted by applicants are, "non-elected by original presentation in that they don't correspond to any of the groups set forth in the restriction requirement."

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The Examiner also acknowledged applicants' arguments in their October 15, 2004 Response, but rejected applicants' contention that M.P.E.P. §§ 818.01, 818.02 and 818.02(a) allow applicants to introduce new claims prior to the beginning of examination on the merits. Although the Examiner acknowledged that a restriction requirement is not an office action on the merits, the Examiner refused to begin examination of applicants' new claims in the absence of an election of the groups in the February 17, 2004 restriction requirement.

Applicants' Response

Applicants initially and for the record maintain their position as set forth in their October 15, 2004 Response. Notwithstanding, applicants proceed to reply to the February 17, 2004 restriction requirement.

As a preliminary matter, applicants point out that their new claims 26-49 filed June 17, 2004 are drawn to transgenic plants, a process of their preparation and a process of their use, in compliance with 37 C.F.R. § 1.141. Transgenic plant claims and process of their preparation claims were also pending as of the issuance of the February 17, 2004 restriction requirement. Thus, applicants' response to the February 17, 2004 restriction requirement which follows is consistent with applicants' new claims 26-49.

Turning now to the restriction requirement, as of February 17, 2004, claims 1-25 were pending in the subject application. Specifically, claims 1-12 were directed to an isolated nucleic acid; claims 13-15 were directed to a gene construct comprising the isolated nucleic acid; claims 16-20 were directed to a method of altering the level of epoxy fatty acids in a plant using the

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isolated nucleic acid; claims 21 and 23-25 were directed to a plant transformed with the isolated nucleic acid; and claim 22 was directed to a progeny of such plant. Claims 2-25 incorporated the limitations of claim 1 by specifically referring back to claim 1. Thus, claim 1 was the sole independent claim.

The February 17, 2004 restriction requirement required restriction between four (4) allegedly distinct inventions, which were grouped as follows:

- I: claims 1-9, 12-14 and 16-25 drawn to products and methods relating to SEQ ID NO. 1 or encoding SEQ ID NO: 2;
- II: claims 1-9, 12-14 and 16-25 drawn to products and methods relating to SEQ ID NO. 3 or encoding SEQ ID NO: 4;
- III: claims 1-9, 12-14 and 16-25 drawn to products and methods relating to SEQ ID NO. 5 or encoding SEQ ID NO: 6; and
- IV: claims 1-25 drawn to products and methods relating to SEQ ID NO. 19 or encoding SEQ ID NO: 20.

All of the purported distinct groups were classified in class 800, subclass 281, i.e. the same class.

The Examiner then proceeded to allege that inventions I-IV are unrelated. The only support for this assertion was the Examiner's assertion that, "[i]nventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have *different modes of operation, different functions, or different effects* (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of Groups I-IV are drawn to *different sequences that are structurally and physically*

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*distinct.*" Immediately evident however, is that in the February 17, 2004 restriction requirement neither a "structural" nor a "physical" distinction between the sequences was shown to result in "different modes of operation, different functions, or different effects."<sup>1</sup> Absent such a showing, however, the February 17, 2004 restriction requirement is improper for failing to set forth a basis. Accordingly, the February 17, 2004 restriction requirement should be deemed moot and withdrawn.

The February 17, 2004 restriction requirement is at most an election of species requirement.

Besides being improper for failing to state a basis, the February 17, 2004 restriction requirement is really an election requirement. Recognizing that the purported "restriction" requirement would more properly be an election requirement, the Examiner proceeded to state:

Applicants are reminded that nucleotide sequences encoding different proteins are structurally distinct chemical compounds and are unrelated to one another. These sequences are thus deemed to normally constitute **independent and distinct** inventions within the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such nucleotide sequence is presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. 121 and 37 1.141 et seq. This requirement is not to be construed as a requirement for an election of species, since each nucleotide and amino acid sequence is not a member of a single genus of invention, but constitutes an independent and patentably distinct invention. (Emphasis in original)

Immediately apparent, however, is the lack of any citation to a legal basis supporting the Examiner's attempt to classify the requirement as one for "restriction" rather than for a species

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<sup>1</sup> Indeed, such a showing cannot be made because SEQ ID NOs:1, 3, 5 and 19 belong to the family of plant fatty acid epoxygenase genes.

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election. Also apparent is the lack of any explanation for alleging that, "each nucleotide and amino acid sequence is not a member of a single genus of invention, but constitutes an independent and patentably distinct invention." No justification or explanation of either of these blanket conclusions is present in the February 17, 2004 restriction requirement.

Applicants respectfully point out that all of the nucleotide sequences that the Examiner purported to "not be a member of a single genus of invention," are classified in the specification as belonging to the family of plant fatty acid epoxygenase genes. Applicants claims are organized on this basis, i.e. claim 1 recited an "isolated nucleic acid that encodes a plant fatty acid epoxygenase polypeptide." Subsequent claims then define specific examples of this genus, such as SEQ ID Nos: 1, 3, 5 and 19.

Accordingly, the February 17, 2004 restriction requirement is at most an election requirement. Its characterization as a "restriction" 1) is not supported by any explanation, and, more importantly, 2) is contradicted by applicants' specification and claims.

Consistent with their position that the February 17, 2004 requirement is an election of species requirement, and predicated on the understanding that their generic claims would also be examined, applicants are willing to elect a species for initial examination. If this is acceptable, and in the interest of advancing prosecution of this application, applicants invite the Examiner to telephone the undersigned at which time applicants are prepared to make the species election.<sup>2</sup>

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<sup>2</sup> The undersigned was unsuccessful contacting the Examiner on January 27, 2004, and left a voice message in which the undersigned requested a call back at the Examiner's convenience. As of this filing on January 31,

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Applicants' new claims 26-49 filed June 17, 2004 are amenable to a species election should the Examiner so require. New claims 26-49 are drawn to transgenic plants, a process of their preparation and a process of their use, in compliance with 37 C.F.R. § 1.141. Transgenic plant claims were also pending as of the issuance of the February 17, 2004 restriction requirement. Applicants' new claims, thus, merely better define applicants' invention which was pending prior to the issuance of the February 17, 2004 restriction requirement.

Election

Finally, should the Examiner 1) continue to maintain that the February 17, 2004 restriction requirement is proper and not mooted by the lack of any basis for it, and 2) refuse to classify it as an election of species requirement, applicants in the interest of advancing prosecution but with traverse on the grounds detailed herein, hereby elect all of SEQ ID NOs: 1, 3, 5 and 19 pursuant to M.P.E.P. § 803.04, 8<sup>th</sup> Ed., Rev. 2, May 2004, along with sequences which are patentably indistinct from, and encode the same protein as, the selected sequences, i.e. generic sequences. Although applicants' new claims 26-49 filed June 17, 2004 are drawn to an exemplified transgenic plant of certain characteristics, the claims could be understood as amenable to this election using the same strained logic used to apply the restriction to the previously pending transgenic plant claims.

M.P.E.P. § 803.04, 8<sup>th</sup> Ed., Rev. 2, May 2004, contains the very same language the Examiner has reproduced on page 3 of the February 17, 2004 restriction requirement without citation, and

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2005, the undersigned has not been able to discuss this with the Examiner.

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also contains language the Examiner omitted in the February 17, 2004 restriction requirement. M.P.E.P. § 803.04, 8<sup>th</sup> Ed., Rev. 2, May 2004, in part, is reproduced below, with the text corresponding to that used by the Examiner appearing in **bold**:

**Nucleotide sequences encoding different proteins are structurally distinct chemical compounds and are unrelated to one another. These sequences are thus deemed to normally constitute independent and distinct inventions within the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such nucleotide sequence is presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.141 et seq.** Nevertheless, to further aid the biotechnology industry in protecting its intellectual property without creating an undue burden on the Office, the Commissioner has decided *sua sponte* to partially waive the requirements of 37 CFR 1.141 et seq. and permit a reasonable number of such nucleotide sequences to be claimed in a single application. See *Examination of Patent Applications Containing Nucleotide Sequences*, 1192 O.G. 68 (November 19, 1996).

It has been determined that normally ten sequences constitute a reasonable number for examination purposes. Accordingly, in most cases, up to ten independent and distinct nucleotide sequences will be examined in a single application without restriction. In addition to the specifically selected sequences, those sequences which are patentably indistinct from the selected sequences will also be examined. Further-more, nucleotide sequences encoding the same protein are not considered to be independent and distinct inventions and will continue to be examined together.

Clearly, "up to ten independent and distinct nucleotide sequences will be examined in a single application without restriction." Furthermore, "sequences which are patentably indistinct from the selected sequences will also be examined." Applicants have elected merely four, along, of course, with any patentably indistinct nucleotide sequences and those encoding the same protein. Applicants look forward to their examination on the

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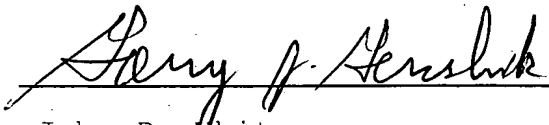
merits.

Summary

In summary, applicants maintain that the February 17, 2004 restriction requirement 1) is improper for failing to set forth a basis; 2) is at most an election requirement; and, 3) in any event, stands as replied to by applicants' election of SEQ ID NOs: 1, 3, 5 and 19, along with sequences which are patentably indistinct from, and which encode the same protein as, the selected sequences, i.e. generic sequences, pursuant to M.P.E.P. § 803.04, 8<sup>th</sup> Ed., Rev. 2, May 2004.

No fee is deemed necessary in connection with the filing of this Response. However, if any fee is required, authorization is hereby given to charge the amount of any such fee to Deposit Account No. 03-3125.

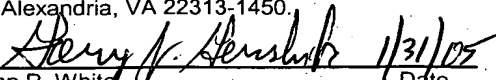
Respectfully submitted,



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I hereby certify that this correspondence is being deposited this date with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to:

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